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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/407, 327 09/28/99 LOWELL

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EXAMINER

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GRASER, J

ART UNIT	PAPER NUMBER
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1641

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DATE MAILED:

02/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/402,347	Applicant(s) Lowell et al.
Examiner Graser, Jennifer	Group Art Unit 1641

Responsive to communication(s) filed on _____.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-16 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-16 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Priority

1. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading, for example "This is a continuation of Application No. , filed , now US Patent No. , which is a continuation of...etc." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Specification

2. The disclosure is objected to because the margins are set very close together wherein the text appears to be a single column in the middle of the page. Appropriate correction is requested.

Additionally, the first line of the specification is missing information, specifically the serial number of the priority data. Further, page 7, lines 14-15, is missing information. The serial no. of the application should be filled in the blanks.

Response to Arguments concerning filing date and incorporation by reference

3. Applicants stated in the prosecution of parent case 08/677,302 that the written text and figures of the instant application include those of the PCT/US93/0402 application (PCT parent application) as well as those of the article appearing at pages 2390-239 of Infection and Immunity, Vol. 61, No. 6, June 1993. Applicants have argued that since the content of the instant application is the same as the PCT parent application and the text of the incorporated reference, they are entitled to the 10/29/93 filing date of the PCT application. These arguments have been

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fully and carefully considered and are effective in overcoming the former objection to the incorporated material. The instant application is a continuation application and has an effective filing date of October 29, 1993, i.e., the same as PCT/US93/0402. The PCT application was reviewed under U.S. law and therefore the incorporated material is considered part of the instant specification.

Claim Rejections - 35 USC § 112

4. Claims 7-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-9 lack antecedent basis as claim 5 does not contain a vaccine. Amending claims 7 and 8 to depend from claim 6 (not 5) would obviate this rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 4-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Zollinger et al (4,707,543).

Zollinger discloses detoxified lipopolysaccharide-outer membrane protein complexes and capsular polysaccharide-outer membrane protein complexes wherein the lipopolysaccharide is

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noncovalently bonded to the protein whereas capsular polysaccharides can either be noncovalently or covalently bonded to the protein to form a complex (col. 4, lines 15-29). It is disclosed that the complexes are generally derived from Gram-negative bacteria, *N.meningitidis* Group B, *Neissera gonorrhoeae* are exemplified. Zollinger et al exemplify the use of outer membrane proteins purified by detergent extraction and ammonium sulfate precipitation and are known as "proteosomes". See Example 1 . The compositions were used as vaccines and given subcutaneously (col. 7, line 60-col. 8, line 30).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2, 3, 14, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zollinger et al (4,707,543) in view of Cohen et al. (J. Infect. Dis., 1988, 157(5): 1068-1071) and Black et al (J. Infect. Dis., 1987, 155(6): 1260-1265) and in further view of Ruegg et al (J. Immunolog. Methods, 1990, 135: 101-109).

The teachings of Zollinger et al are set forth above. However, they do not particularly exemplify compositions and/or vaccines wherein the LPS is from *Shigella*, particularly *S.flexneri* or *S.sonnei*.

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Cohen teaches that *S.flexneri* or *S.sonneni* are causative agents of shigellosis. The reference teaches that the levels of antibodies to LPS present in subjects before or at the onset of an outbreak of shigellosis were associated with significant protection against the disease (p. 1070, col. 2). The reference further discloses that preexisting levels of antibodies to LPS indicate group-specific protection against shigellosis and that a previous report showed that serotype- and serogroup-specific immunity was conferred by the O-polysaccharide chain of LPS (p. 1070, col.2).

Black et al disclose that they modified attenuated *Salmonella typhi* strain Ty21a to express the form I O polysaccharide antigen of *S.sonneni* and administered it as a bivalent, live oral vaccine (abstract). Vaccines had serum and local intestinal immune responses to *S.sonneni* lipopolysaccharide and the presence of specific serum IgA or IgG antibody before challenge with pathogenic *S.sonneni* was correlated with protection from illness (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made that one could use LPS from *S.flexneri* or *S.sonneni* in the detoxified lipopolysaccharide-outer membrane protein complexes disclosed by Zollinger because Zollinger teaches that LPS from any Gram negative bacteria could be used in the complexes and Cohen and Black specifically teach that the LPS from *S.flexneri* or *S.sonneni* is responsible for protection from shigellosis. One of ordinary skill in the art would have been further motivated to use the *Shigella* LPS-proteosome complex because Ruegg et al specifically disclose that proteosomes have an adjuvant-like effect when complexed with lipopeptides without the need of additional adjuvants and one of ordinary

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skill in the art would expect a multivalent preparation to enhance the immunogenic activity of an antigen and therefore enhance the immunity of the LPS. Black et al also disclose that the oral administration route is an effective route for the treatment of shigellosis as it can allow for the *Shigella* to cross the mucosa thereby bringing the organism into direct contact with lymphoid tissues which may stimulate a stronger protective response.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,985,284 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims differ only in that they recite a "non-detoxified antigenic lipopolysaccharide" as opposed to just a "lipopolysaccharide". The scope of the claims is therefore not patentably distinct.

Art Made of Record

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11. The following art was applied during the prosecution of 08/677,302:

A Rule 132 Katz Declaration was received in 08/677,302 and was sufficient to overcome the former 35 U.S.C. § 102(a) rejection as being anticipated by Orr et al (Infect. Immun., June 1993, 61(6): 2390-2395) and the former 35 U.S.C. 102(a) as being anticipated by Orr et al (93rd General Meeting of the American Society for Microbiology, Atlanta, Georgia, USA, May 16-20, 1993. Abstract Gen. Meet. Am Soc. Microbiol. #152). :

- a) Orr et al (93rd General Meeting of the American Society for Microbiology, Atlanta, Georgia, USA, May 16-20, 1993. Abstract Gen. Meet. Am Soc. Microbiol. #152).
- b) Orr et al (Infect. Immun., June 1993, 61(6): 2390-2395)
- c) Mallett et al (Infection and Immunity, June 1995, 63(6): 2382-2386)
- d) Livingston et al (Vaccine, 1993, 11(12): 1999-1204).

The prior art cited above was sent to applicants during the prosecution of the parent case 08/677,302. Accordingly, only the newly cited art, US Patent 5,985,284, is being mailed to Applicants at this time.

12. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art . Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1641 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jennifer Graser
JENNIFER GRASER
PATENT EXAMINER
11/28/04